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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/550,317

09/22/2005

Raphael Donati

125017

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25944 7590 06/25/2008

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                       |                                      |  |
|------------------------------|---------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/550,317  | <b>Applicant(s)</b><br>DONATI ET AL. |  |
|                              | <b>Examiner</b><br>Bao-Thuy L. Nguyen | <b>Art Unit</b><br>1641              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The amendment dated 27 February 2008 have been received.
2. Claims 27-29 have been added.
3. Claims 14-29 are pending.
4. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims and/or arguments.

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 14-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Eisinger et al (US 4,943,522).

Eisinger discloses a device and method for using the same in an immunoassay. The device comprising a porous solid support (i.e. bibulous material) having a sample contact area, a detection are and a liquid absorbent material. See column 4, lines 42-64. The label is any molecule bound to a specific binding member and can be an enzyme, a liposomes, or visible colored particles, etc. See column 5, lines 19-36. Eisinger teaches visible particles added to, or applied before or after, the sample and used for detection by being trapped in the

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indicator zone by the binding pair complex. See column 5, lines 37-48.

Particularly, Eisinger discloses protocols comprising (1) analyte in the sample binds specifically to the member affixed to the indicator zone; a label is then added to detect the bound analyte, i.e. in a sandwich immunoassay (see column 8, lines 38-41); (2) the sample is spiked with a labeled form of analyte and the labeled form bound the member affixed in the indicator zone is detected, i.e. a competition assay; (3) analyte carries with it the means of its own detection, or may first be reaction with label. The label-bearing analyte can then be bound specifically to the affixed member; and (4) detectable particles may be used to detect an unlabeled complex of analyte with binding pair member in the indicator zone. See column 8, lines 31-60. The device of Eisinger is disposed in a housing having means for observing the results. See column 10, line 51 through column 11, line 23. Eisinger also teaches that developer solutions or diluents, if required, is added after the sample and labels are added. See column 11, lines 24-48 and column 16, lines 64-68.

### *Response to Arguments*

7. Applicant's arguments filed 27 February 2008 have been fully considered but they are not persuasive.

Applicant argues that Eisinger fails to disclose an instance where a label and a sample are added separately, successively and extemporaneously.

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This argument is not persuasive. Eisinger specifically teaches at column 19, lines 1-18 that for hCG assay, a urine sample is applied to the application zone and allowed to flow through an indicator zone containing anti-hCG antibodies. After washing, a labeled anti-hCG is then applied to the indicator zone, either directly or by flowing from the application, and if needed, followed by developing reagents. Clearly, this is a disclosure of an instant where a label and a sample are added separately, successively and extemporaneously.

### *Conclusion*

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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/Bao-Thuy L. Nguyen/

Primary Examiner, Art Unit 1641

June 7, 2008